b.) Remarks

The claims have been amended in order to recite the present invention with the specificity required by statute. The subject matter of the amendment to claims 1, 6 and 18 may be found at specification page 23, lines 6-11. Accordingly, no new matter has been added.

Claims 1, 4, 5, 7, 9-11, 28-30 and 32 are rejected under 35 U.S.C. §112, first and second paragraphs, as failing to comply with the enablement and written description requirements, since the Examiner contends "delaying the onset of arthritis" is not described in the specification. In response, Applicants respectfully submit those of ordinary skill readily appreciate that subject matter from Example 3 and Table 2 at specification pages 38-40. Nonetheless, solely in order to reduce the issues and expedite prosecution, that phrase has been deleted from claims 1, 3-5, 7, 18, 20-22, 28 and 31. Accordingly, this rejection is mooted.

Claims 1, 4-7, 9-11, 28-30 and 32 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Sorgente (U.S. Patent No. 6,162,787) and Guardia (Il Farmaco) in view of Balado (Rev. Fac. Cienc. Quim. in further view of Matsuda (Chem. Pharm. Bull.) for the reasons set forth in the previous Office Action.

In support of the rejection the Examiner states Sorgente teaches orally administering glycosamine and condroitin sulfate to treat arthritis, and that such can be formulated as a food or drink. The Examiner acknowledges Sorgente does not teach any compositions containing *Hydrangea macrophylla* extract, but this deficiency is said to be addressed by the combination of Guardia (showing dietary flavonoids and rutin are

effective in reducing inflammation) and Balado (showing rutin is found in *Hydrangea macrophylla* blossoms).[1]

Previously, Applicants argued that the present invention achieves unexpectedly superior results over the closest prior art, relying in part on example 3 at specification pages 38-40. In response, such showings were not found persuasive. To the contrary, according to the Examiner, the

> decrease in the arthritic score for the claimed composition (group 4) is not greater than the additive effects of groups 2 and 3. As compared to group 1, group 2 results in 1.74 point decrease. As compared to group 1, group 3 results in a 1.0 point decrease. Using both compositions together at least a 2.74 decrease would be expected. Group 4 results in a 2.74 point decrease. Therefore, the results are not unexpected.

Accordingly, to establish for the record why the results of example 3 are, in fact, unexpectedly superior, Applicants enclose herewith a Declaration under Rule 132 of Dr. Toshikazu Kamiya.

As explained in Dr. Kamiya's Declaration, the animals of Group 4 were administered their active ingredients at <u>one-half</u> the dosage of the animals of Groups 2 and 3. Accordingly, the expected reduction in arthritis achieved by the animals of Group 4 should have been one-half of that evidenced. Since the present invention achieves <u>twice</u> the expected activity of Groups 2 and 3, patentable unobviousness has been established on the record.

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[1] Matsuda is cited as showing "that chemical constituents with antihistamine activity were extracted from the leaves of *Hydrangea macrophylla* Seringe var.Thunbergii Makino. Frankly speaking, it is unclear why this is relevant since the Examiner has cited no relevance showing that antihistamines are indicated for treating arthritis. Citation of such a reference and/or provision of an Examiner's affidavit under MPEP §2144.03 is respectfully requested.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 1-7, 9-11, 18, 20-22 and 28-31 remain presented for continued prosecution with rejoinder of withdrawn claims 3, 18, 20-22 and 31 being respectfully requested.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

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